(1074)

MAR - 7 2000

STD Manufacturing, Inc., Confidential - TRADE SECRET

510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The assigned 510(k) number is: K000603

Submitted by: Jim Lousararian
COO
STD Manufacturing, Inc.
1063 Turnpike Street
Stoughton, MA 02072

Telephone #:(781) 828-4400 Facsimile #:(781) 344-5895

Date Prepared: 22 February 2000

Establishment Registration Number: STD Manufacturing is located at 1063 Turnpike Street, Box 420, Stoughton, MA 02072. We are registered with the Food and Drug Administration as Establishment Number 1222928.

Classification Name:

Applier, Staple, Surgical/ Stapler, Surgical
General and Plastic Surgery
21 CFR § 878.4800 (1999)

Manual Surgical Instrument for general use
Cannula (Sleeve and Obturator)
General and Plastic Surgery
21 CFR § 878.4800 (1999)

Staple, Implantable
General and Plastic Surgery
21 CFR § 878.4750 (1999)

Implantable Clip
General and Plastic Surgery
21 CFR § 878.4300 (1999)

Patch, Pledget and Intracardiac, PETP, PTFE, Polypropylene
Cardiovascular
21 CFR § 870.3470 (1999)

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510(k) SUMMARY (cont.)

Classification Name:	**(continued)** Vascular Clamp Cardiovascular 21 CFR § 870.4450 (1999)
Common/Usual Name:	Stapler/ Clip Applier, with Implantable Staple/ Staple and Pledget
Proprietary Name:	Suction Vascular Stapler and Implantable Staple / Staple and Pledget System
Indication for Use:	The Suction Vascular Stapler and Implantable Staple System Indications for use are to approximate vascular, small tubular structures, and general tissue for achieving hemostatic closure of wound or puncture site to aid healing in minimally invasive or open procedures for full body applications.
Device Description:	The principles of operation and technology incorporated in the Suction Vascular Stapler and Implantable Staple System is equivalent to other staplers, staples, pledgets, and general instruments with the intent of rapid hemostatic closure of general tissues and vascular vessels. This system stabilizes the site or vessel, guides and centers on the wound, and delivers a staple with or without a pledget to the wound site for tissue approximation and closure.

K040603 (3of4)

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510(k) SUMMARY (cont.)

Substantial Equivalence Claim: Suction Vascular Stapler and Implantable Staple System is substantially equivalent to the following legally marketed devices ("Predicate Devices") in terms of safety, effectiveness, and general intended use:

Product: Ligaclip Multiple Clip Applier
Manufacturer: Ethicon Endo-Surgery, Inc.
510(k) Number: K771412
Substantial Equivalence Date: 11/28/77
Intended Use: Approximating tissue for minimally invasive or open surgical procedures.
510(K) data: **Exhibit M**

Product: Auto Suture Modified VCS Clip Applier/ implantable clip
Manufacturer: United States Surgical Corporation
510(k) Number: K962043 / K934087
Substantial Equivalence Date: 09/23/96 / 12/01/93
Intended Use: Device intended for closure of arteriotomies and venotomies, the creation of everting Anastomosis in blood vessels and other small tubular structures, and the approximation of soft tissues.
Summary: **Exhibit O**

Product: Endopath Endoscopic Articulating Stapler
Manufacturer: Ethicon Endo-Surgery, Inc.
510(k) Number: K962258
Substantial Equivalence Date: 09/11/96
Intended Use: Approximating tissue for minimally invasive or open surgical procedures.
Summary of Safety and efficacy: **Exhibit M**

Product: Endopath Disposable Endoscopic Multifeed Stapler
Manufacturer: Ethicon Endo-Surgery, Inc.
510(k) Number: K913469
Substantial Equivalence Date: 09/30/91
Summary: **Exhibit M**

510(k) SUMMARY (cont.)

Substantial Equivalence Claim: (continued)

Product: Staple/Clip, Implantable
Manufacturer: Ethicon Endo-Surgery, Inc.
510(k) Number: K913139 / K890841 / K864102
Substantial Equivalence Date: 09/06/91 / 04/19/89 / 11/05/86
Summary: **Exhibit N**

Product: Auto Suture Modified Endoscopic Fascia Stapler
Manufacturer: United States Surgical Corporation
510(k) Number: K963999
Substantial Equivalence Date: 11/27/96
Intended Use: Device intended for approximating tissue in endoscopic and open procedures.
Summary: **Exhibit O**

Product: FemoStop System/ Femoral Compressor Device/Clamp
Manufacturer: RADI Medical Systems AB
510(k) Number: K983471
Substantial Equivalence Date: 02/23/99
Intended Use: Device is indicated for use in the compression of the femoral artery or vein after vessel cannulation, and in ultrasound-guided compression repair of a femoral artery pseudoaneurysm.
Summary of Safety and efficacy: **Exhibit P**

Product: Flexipath Obturator and Sleeve
Manufacturer: Ethicon Endo-Surgery, Inc.
510(k) Number: Class I, Exempt
Substantial Equivalence Date: N/a

Product: Pledget
Manufacturer: Deknatel, Inc.
510(k) Number: Unknown
Substantial Equivalence Date: Unknown

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 7 2000

Mr. Jim Lousararian
Chief Operating Officer
STD Manufacturing
1063 Turnpike Street
Stoughton, Massachusetts 02072

Re: K000608
Trade Name: Suction Vascular Stapler and
Implantable Staple System
Regulatory Class: II
Product Code: GDW
Dated: February 22, 2000
Received: February 23, 2000

Dear Mr. Lousararian:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000608

Device Name: **Suction Vascular Stapler and Implantable Staple System**

Indications for Use:

The Suction Vascular Stapler and Implantable Staple System Indications for use is to approximate vascular, small tubular structures, and general tissue for achieving hemostatic closure of wound or puncture sites to aid healing in minimally invasive or open procedures for full body applications.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

MRO for STD

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000608

Prescription Use X
(Per 21 CFR 801.109

Over-The Counter Use _____

(Optional Format 1-2-96)